

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/035039

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07K14/195 C07K14/245 A61K39/39 A61K39/02 G01N33/483

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07K A61K G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, EMBASE, BIOSIS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/044939 A1 (PIZZA MARIAGRAZIA ET AL) 18 April 2002 (2002-04-18)	1,2,7, 12-15, 19, 25-28, 43-48
A	paragraph '0030! the whole document	3-6, 8-11, 16-18, 20-24, 29-39, 49-60
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Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

## \* Special categories of cited documents:

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document but published on or after the international filing date

\*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*Z\* document member of the same patent family

Date of the actual completion of the international search

14 April 2005

Date of mailing of the international search report

02/05/2005

Name and mailing address of the ISA

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International Application No  
PCT/US2004/035039

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	PRONK S E ET AL: "HEAT-LABILE ENTEROTOXIN OF ESCHERICHIA-COLI CHARACTERIZATION OF DIFFERENT CRYSTAL FORMS" JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 260, no. 25, 1985, pages 13580-13584, XP002323951 ISSN: 0021-9258 abstract; table II	1,2,7, 12-15, 19, 25-28, 43-48
A	the whole document	3-6, 8-11, 16-18, 20-24, 29-39, 49-60
A	----- WANG WEI: "Instability, stabilization, and formulation of liquid protein pharmaceuticals" INTERNATIONAL JOURNAL OF PHARMACEUTICS (AMSTERDAM), vol. 185, no. 2, 20 August 1999 (1999-08-20), pages 129-188, XP002323952 ISSN: 0378-5173 cited in the application page 177, column 2, paragraph 3 - page 178, column 2, paragraph 2	1-39, 43-60
A	----- GLENN G M ET AL: "Transcutaneous immunization with bacterial ADP-ribosylating exotoxins as antigens and adjuvants" INFECTION AND IMMUNITY, AMERICAN SOCIETY FOR MICROBIOLOGY, WASHINGTON, US, vol. 67, no. 3, March 1999 (1999-03), pages 1100-1106, XP002110054 ISSN: 0019-9567 the whole document	1-39, 43-60
A	----- KRUEGER K M ET AL: "THE FAMILY FO BACTERIAL ADP-RIBOSYLATING EXOTOXINS" CLINICAL MICROBIOLOGY REVIEWS, WASHINGTON, DC, US, vol. 8, no. 1, January 1995 (1995-01), pages 34-47, XP001146599 ISSN: 0893-8512 the whole document	1-39, 43-60

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### Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **47-48**  
because they relate to subject matter not required to be searched by this Authority, namely:  
**Although claims 47 and 48 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.**
2. ☒ Claims Nos.: **40-42**  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
**see FURTHER INFORMATION sheet PCT/ISA/210**
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

## Continuation of Box II.1

Although claims 47 and 48 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

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## Continuation of Box II.2

Claims Nos.: 40-42

Claims 40-42, which relate to stabilising agents identified by the (screening) methods of claims 37-39, are "reach-through" claims which attempt to define a product by an effect to be achieved. Such a definition is in fact a mere statement of the problem underlying the claims and is not considered to be a clear definition in the sense of Article 6 PCT. Moreover, the skilled person would have to characterise all potential agonists / antagonists, without any effective pointer to their identity and to test every known compound, as well as every conceivable future compound, for this activity to see if it falls within the scope of the claims. Moreover, the description does not provide any meaningful disclosure of suitable compounds identified by the method of claims 37-39.

Hence, it cannot ascertain whether or not a particular product falls within the scope of claims 40-42, so that a meaningful search of the subject-matter of said claims 40-42 is not possible.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/035039

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002044939 A1	18-04-2002	IT 1253009 B	10-07-1995
		US 2004137017 A1	15-07-2004
		AU 6238896 A	05-02-1997
		EP 0835314 A1	15-04-1998
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		AT 277183 T	15-10-2004
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		EP 1484404 A1	08-12-2004
		EP 0620850 A1	26-10-1994
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		US 6149919 A	21-11-2000